REMARKS

The Office Action of October 15, 2007, has been received and carefully reviewed. Claims 1-16 and 41-55 are withdrawn. New independent claim 56 has been added and is fully supported by original claim 33 and Applicant's specification.

Applicant has amended claim 17 by insertion of the phrase "large neutral amino acid" before the acronym "LNAA" to clarify and define the metes and bounds of the claim.

Applicant has amended claim 22 by inserting the phrase, "in an amount between about 5 to 30 mg per 500 mg of LNAA supplement" after the term "Lys". Support for this amendment can be found in claims 33 and 34. Claim 34 has been cancelled. No new matter has been added by these amendments.

The Examiner objected to the title of the specification as not being sufficiently descriptive. Applicant has amended the title to be further descriptive of the fact that Large Neutral Amino Acids are part of the composition. Applicant requests withdrawal of the objection.

Rejections under 35 U.S.C. §102(b)

The Examiner rejected claims 17-36 under 35 U.S.C. §102(b), as being anticipated by Wachtel et al. (DE 4037447). According to the Examiner, Wachtel et al. teaches an amino acid composition consisting of histidine, isoleucine, valine, threonine, methionine, leucine, etc. and teach weight ratios, which the

examiner calculates to be within the claimed ranges of Applicant and therefore anticipated by Wachtel et al. Applicant respectfully traverses this rejection.

Applicant objects to the Examiner's citation of a German patent printed in German, without providing Applicant with suitable English translations of either the abstract or the complete text. Untranslated scientific papers should not be used as a basis for rejections, under MPEP §706.02.

Applicant believes that the Examiner has misread the Wachtel et al. reference, and the weight ratios are not as the Examiner has claimed. According to Applicant's Danish associate, the specification of Wachtel et al. states, "So können die Anteile für Lysin, Isoleucin, Leucin, Valin und Tyrosin jeweils um bis zu +/- 10 % und die Anteile für die übrigen Aminosäuren um bis zu +/- 20 % von dem genannten Wert abweichen." Thus, as translated states, "the weight ratios may vary with +/- 10 % and +/- 20 %, respectively, of the mentioned values." Even without a German translation of the Table at column 7 of Wachtel et al., it would be clear to one of ordinary skill in the art, that when the weight percent is given as 14.5 +/- 10%, this does not mean that the weight of the substance varies from 4.5% to 24.5%. If this were correct, then it would mean that the amount of histidine for example, (5.0 +/- 20 %) could be less than 0 %, i.e. negative 15.0 %, which obviously makes no sense. What is meant in Wachtel et al. is that the weight percent (for example 14.5%) varies by 10%, or +/- 1.45%, giving a range of 13.05% to 15.95%. Applicant submits that the weight ratios adjusted for a 500 mg tablet according to

Wachtel et al. are as follows:

Lysine: 72.5 mg (65.3-79.8 mg)
Histidine: 25 mg (20-30 mg)
Isoleucine: 59.5 (53.6-65.5 mg)
Leucine: 101 mg (90.9-111.1 mg)
Methionine: 24.5 mg (19.6-29.4 mg)
Threonine: 47.5 mg (38-57 mg)
Valine: 72 mg (64.8-79.2 mg)
Tryptophan: 18 mg (14.4-21.6 mg)
Tyrosine: 80 mg (72-88 mg).

As such, the ratio of leucine to valine can be as large as 111.1 to 64.8, viz about 1.71:1, *less* than 2:1. The weight ratio of leucine to isoleucine can be as large as 111.1 to 53.6, viz. about 2.07:1, *less* than 3:1.

In view of Applicant's amended claim 22, the claimed composition contains substantially less lysine than the supplement taught in Wachtel et al. Claims 23 to 32 are all dependent on claim 22. Applicant submits that claims 22 to 32 cannot be anticipated by Wachtel et al. because all the features of Applicant's claims are not taught by Wachtel et al.

With regard to claim 33, Applicant again points out that the Examiner has miscalculated the weight ratios. Thus, the comparison in Table 1 of the Office Action should correctly be as follows:

Amino acid	LNAA of claim 33 (mg in 500 mg total)	Wachtel et al (mg in 500 mg total)

Tyrosine	100-290	72-88
Tryptophan	25-75	14.4-21.6
Methionine	15-50	19.6-29.4
Isoleucine	15-55	53.6-65.5
Threonine	15-50	38-57
Valine	15-55	64.8-79.2
Leucine	15-200	90.9-111.1
Histidine	10-30	20-30
Lysine	5-200	65.3-79.8

Thus, the content of tyrosine and tryptophan is substantially higher in Applicant's supplement of claim 33 than taught by Wachtel et al., and the content of valine of Applicant's supplement is substantially lower.

Since claim 33 is dependent from claim 22, and claim 22 was amended, Applicant has also amended claim 33 by inclusion of the feature of claim 34 wherein the lysine content is between about 5 mg to about 30 mg lysine per 500 mg tablet. Claims 35 to 40 all are dependent on claim 33. Therefore, Applicant submits that in view of Applicant's amended claims, Wachtel et al. do not teach each and every element of Applicant's claimed invention, and therefore, cannot be anticipated by Wachtel et al. Applicant respectfully requests withdrawal of this rejection.

Claim Rejections under 35 U.S.C. § 103(a)

The Examiner has rejected claims 37-40 as being unpatentable under 35 U.S.C. § 103(a), over Wachtel et al., in view of Ghadimi, and further in view of Nakaki et al. According to the Examiner, Wachtel et al. teach a supplement which anticipates the ranges of all the amino acids except arginine. Ghadami is offered by the Examiner for teaching a LNAA supplement which contains

arginine. The Examiner argues that it would have been obvious to one of ordinary skill at the time the invention was made, to add arginine in the amount taught in Ghadimi to the composition of Wachtel et al. because they are both amino acid compositions and, further, because Nakaki et al. teach that treatment of PKU is started from the time a person is an infant, and arginine is a necessary amino acid for growing children. Applicant respectfully traverses this rejection.

The rejection in the present application is based on 35 U.S.C. §103(a). Under U.S. patent law, the burden is on the Examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references. *In re Deuel,* 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). Only after that burden is met must the applicant come forward with arguments or evidence in rebuttal. *Id.* To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

The Examiner's comparison of the supplement in claim 37 to that taught by Wachtel et al. is also based on the same miscalculation as discussed above. Thus, the comparison in Table 2 of the Office Action should correctly be as follows:

Amino acid	LNAA of claim 37 (mg in 600 mg total)	Wachtel et al. (mg in 600 mg total)
Tyrosine	100-290	86.4-105.6
Tryptophan	30-90	17.3-25.9
Methionine	25-75	23.5-35.3

Isoleucine	15-45	64.3-78.5
Threonine	15-50	45.6-68.4
Valine	15-50	77.8-95.0
Leucine	40-200	109.1-133.3
Histidine	15-45	24-36
Arginine	15-50	0

From the above Table, it is clear that the content of tryptophan and arginine in Applicant's claimed invention is substantially higher than taught by Wachtel et al., and that the content of isoleucine and valine recited in Applicant's claims are substantially lower. In addition, claims 39 to 40 relate to a 600 mg supplement also including 5-200 mg lysine. Applicant submits that because the combination of Wachtel et al., in view of Ghadimi, and Nakaki et al. do not teach each and every element of Applicant's claimed invention, the combination cannot render claims 37-40 *prima facie* obvious, and therefore, Applicant respectfully requests withdrawal of this rejection.

Furthermore, Applicant submits that Wachtel et al. anticipate *neither* the ranges of amino acids *nor* the content of arginine, and therefore, it would not have been obvious to one skilled in the art, at the time of the invention, to adjust both the amount of certain amino acids in the composition of Wachtel et al. and to add arginine in the amount taught by Ghadami, thereby providing LNAA supplements with improved effect in PKU patients compared to traditional PKU-compositions. Moreover, even though arginine is known as a necessary nutritional supplement for infants and growing children who cannot synthesize arginine fast enough to support growth requirements, Applicant states that it would *not*

have been obvious to one skilled in the art *both* to adjust the amount of certain amino acids in the composition of Wachtel et al. *and* to add arginine in the amount taught by Ghadimi, because Nakaki et al. do not teach anything about the dose range for arginine in children. All Nakaki et al. teach is possible mechanisms of action for the hypotensive effects of administration of arginine intravenously. There is no teaching or suggestion of any particular amount of arginine that should be contained in a nutritional supplement, nor any information about providing LNAA supplements with improved effect to PKU patients as compared to traditional PKU-compositions. As such, one of ordinary skill in the art would have had no motivation to combine the teachings of Ghadami and Nakaki et al. with Wachtel et al., and would not have had any reasonable expectation of success in trying such a combination. Applicant respectfully requests withdrawal of this rejection.

Applicant believes the currently pending claims are now in condition for allowance. If the Examiner has any questions regarding this response, the Examiner is invited to telephone Applicant's counsel at the number provided below.

Respectfully submitted,
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